EXHIBIT E

January 7, 2013

SUPERIOR COURT OF NEW JERSEY
ATLANTIC COUNTY/CIVIL DIVISION
DOCKET NO. ATL-L-6966-10

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LINDA GROSS and JEFFREY GROSS, Plaintiffs, v. GYNECARE, ETHICON, INC., JOHNSON & JOHNSON, and JOHN DOES 1-20, Defendants.	:STENOGRAPHIC :TRANSCRIPT OF: : : : - HEARING - : : :

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PLACE: ATLANTIC COUNTY COURTHOUSE
1201 Bacharach Boulevard
Atlantic City, New Jersey

DATE: January 7, 2013

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B E F O R E:

THE HONORABLE CAROL E. HIGBEE, P.J. Cv.

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difficult to decide specifically how you draw the line, but we do know that, you know, overall, that's not an appropriate approach.

THE COURT: To each of these experts that you've named, you can prepare an order that indicates that the motion to exclude their testimony is denied at this time, that the -- without prejudice to the defense to object to any particular line of questioning at the time of trial, and that the witnesses are precluded from making inflammatory or judgmental statements about the corporation and/or from stating their own belief as to what the company's personal interpretation or intent was. But they can certainly lay it out. They can certainly define certain words and terms and things like that, if it's a medical point of view or if it's, you know, something about a particular proceeding, they could put it in context.

So I really think we have to basically play it question by question at the time of trial. But counsel should make sure that its witnesses understand that both -- you know, when they were doing this, they were really trying to do XYZ or they were really trying to hide this or -- you know, that as interpretations are not

appropriate. And we've already really ruled on that. I think I already said about intent previously in another motion.

So that and inflammatory statements about their -- this shows how evil they are or, you know, they were bad actors, or this shows how greedy they are, anything like that shouldn't be part of an expert's testimony.

MR. SLATER: Understood.

THE COURT: So having said that, give those instructions to your experts. And then if there's a particular question that you feel is outside their expertise or a document that you think the questioning is inappropriate about, we'll just have to deal with it on a step-by-step basis.

MR. ANDERSON: Your Honor, if I could, please. There's a slight difference between Dr. Klinge and Ms. Pence and Dr. Weber in that he was an Ethicon consultant and, therefore, he has expert testimony, also has fact testimony, because he worked with them to develop surgical meshes for greater than ten years. And so there may be some subtle differences there we need to consider when he is testifying. I just wanted to raise that to Your Honor's attention.

THE COURT: No, I agree.

MR. ANDERSON: Thank you.

THE COURT: I still don't think he probably would be somebody you would want to use -- we don't still want inflammatory language.

MR. ANDERSON: Correct.

THE COURT: But when it talks about intent, if he's saying I conferred with the company officials and this is why we did this, then I think that that would obviously be an exception.

MR. ANDERSON: Thank you.

THE COURT: Then he's talking about what his intent was and their intent when they were dealing with him as to what he specifically said, but that will be allowed.

MR. SLATER: One other small question.

These motions that have been filed before Dr. Shott was videotaped for trial, and I carefully cautioned her and she was very -- stayed away from all of it. In fact, her testimony was so narrow that the defense lawyer had to take some time to recast the cross because I stayed away from everything.

The one thing I just wanted to flag

January 17, 2013

SUPERIOR COURT OF NEW JERSEY
ATLANTIC COUNTY/CIVIL DIVISION
DOCKET NO. ATL-L-6966-10

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LINDA GROSS and JEFFREY GROSS, Plaintiffs,	:STENOGRAPHIC :TRANSCRIPT OF:
v.	:
	: - TRIAL -
GYNECARE, ETHICON, INC., JOHNSON & JOHNSON, and JOHN DOES 1-20, Defendants.	:

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PLACE: ATLANTIC COUNTY COURTHOUSE
1201 Bacharach Boulevard
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DATE: January 17, 2013

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B E F O R E:

THE HONORABLE CAROL E. HIGBEE, P.J. Cv.

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involved in the evaluation of the raw data collected in a clinical trial to evaluate the safety and efficacy of a medical device; am I correct?

A Correct.

MS. JONES: Your Honor, that's all I have. I do have an objection.

THE COURT: Okay. Want to come to sidebar?

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(The following occurred at sidebar:)

MS. JONES: Oh.

THE COURT: Do you have another question for her?

MS. JONES: I thought about it. I'll wait. That's all right.

Your Honor, counsel tendered Dr. Weber as an expert in several areas. I do object to her testimony with respect to anything regarding the regulatory aspects of Prolift, the FDA regulations and whether or not the device complied with the regulations and whether or not Ethicon complied with the regulations. I also object on the basis of lack of qualifications to anything relating to the internal design process, compliance with the internal design process, the conduct of that design process by Ethicon.

I further object to the testimony with

respect to polypropylene, the biomaterials aspects of the case, including the porosity of mesh, anything relating to the pathology of mesh. It's on the basis of lack of qualification for her to testify in this area.

Now, let me be candid. This witness has submitted about 600 pages worth of reports in here, and I'm not sure that Mr. Slater is actually tendering her as an expert in all of those areas, but I do object to any regulatory testimony. I object to any testimony with respect to the design defect -- device design safety analysis, the FMEA or all of those for total lack of experience.

MR. SLATER: I'll take them one at a time.

With regard to FDA regulations, she's not going to offer any FDA regulatory opinions. In her testimony she may talk about her familiarity with what was going on with the company. And all of her testimony is going to be couched within the decision-making and the input that would have been or should have been provided by the medical affairs people in the company.

As Your Honor has started to see in this case, and I'll give you a regulatory example, one of the criteria that Sean O'Bryan admitted would have

required him to seek 510(k) clearance would have been if medical affairs had said that clinical study was needed in order to establish substantial equivalence or other criteria for the 510(k) process. She's certainly qualified to give all those opinions.

The person in medical affairs who was responsible to make all of these decisions when the Prolift went on the market was four years out of her residency with no fellowship training, had worked at three general gynecologic clinics in Florida, had never operated on her own with mesh, she had participated in surgeries where she basically assisted another surgeon who used some mesh a few times with some of her patients, this is Charlotte Owens, and that was the person who then made all of the medical affairs decisions related to the Prolift, including the decision that it was safe and effective and could be placed on the market. She gave all of the input to regulatory affairs they relied on in making their decision not to seek FDA 510(k) clearance.

I'll talk about the design assessments. Dr. Weber has intimate knowledge of the process. She is not going to provide an opinion that the process itself was either good or bad, but what she will do is provide the testimony that Piet Hinoul has agreed would

come within the purview of medical affairs.

I will give you the two prime examples. Number one, the DDSA and FMEA was required to address all potential hazards and harms or adverse events that could occur to a woman through the use of the Prolift. The person in the company who was responsible to make sure that that was done was Charlotte Owens of medical affairs.

THE COURT: One second.

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(The sidebar ended.)

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THE COURT: We'll take a short break and let the jury take a break.

(The jury leaves the courtroom.)

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(The following occurred at sidebar:)

MR. SLATER: Charlotte Owens in medical affairs was the person in the company required and relied on to advise and make sure that all of the potential risks were going to be evaluated. And Piet Hinoul said, if that wasn't done, the process was flawed. Dr. Weber will have opinions that Charlotte Owens failed to make sure that all of the potential risks were evaluated, because she's been through the

documents. She understands how to read them. She understands the process -- she's read every single deposition in this case. She's read every document. And she's not going to provide an opinion that DDSA is a good or a bad thing, the FMEA is a good or a bad thing, but what she's going to say is, Charlotte Owens' role was to do this.

She's certainly qualified to offer opinions about whether or not a gynecologist with training and experience that's a small fraction of Dr. Weber's, whether or not she captured what was needed to be captured based on the standards the company followed.

I'll give you another example. Well, I mean, that was I think the things that were specifically addressed.

With regard to polypropylene mesh, Dr. Weber is the co-author of an ACOG practice bulletin that was published in February of 2007, Clinical Management Guidelines for the Treatment of Pelvic Organ Prolapse, in which an analysis was provided of the emerging polypropylene mesh technology -- the emerging polypropylene mesh technology. She's named on the cover of the ACOG practice bulletin, along with another urogynecologist, Scott Smilen. They made recommendations to all gynecologists in the United

States who are members of ACOG in this practice bulletin and drew certain conclusions, including this:

"When choosing the best material for specific procedures, it is critically important that surgeons understand how certain characteristics of materials play a key role in the risk/benefit ratio for various types of surgery. Pore size in surgical mesh is one of the most important factors determining risk of postoperative infection."

I'm just reading some quotes from this.

Another part of it.

"Although several studies have evaluated anterior colporrhaphy with and without mesh or graft materials of different types, because of heterogeneity of materials studied, small sample sizes and short-term follow-up, it is not possible to draw definitive conclusions about the risk versus the benefit of absorbable or permanent synthetic materials in anterior colporrhaphy."

"Given the limited data and frequent changes in the marketed products, particularly with regard to type of mesh material itself, which is most closely associated with several of the postoperative risks, especially mesh erosion, the procedures should be considered experimental and patients should consent

to surgery with that understanding."

She is the person who is recognized on the cover of this practice bulletin. It says, and I'll give the specific cite for the record, this is Clinical Management Guidelines for Obstetrician & Gynecologists, ACOG practice bulletin number 79, February 2007, volume 109, number 2, part 1.

"This practice bulletin was developed by the ACOG committee on practice bulletins, gynecology with the assistance of Scott W. Smilen, MD and Anne M. Weber, MD, MS. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care."

That's in part what it says.

So she has been instrumental in looking into this field. Practice bulletins, as Your Honor I'm sure is aware, in ACOG are given a lot of respect and a lot of importance. They're read, they're looked at. So Dr. Weber certainly has the ability to comment on anything within the company that medical affairs was involved in, because that is the field that she is in. Certainly no one is disputing her expertise in that.

Again, Charlotte Owens was the person who made all of the critical medical decisions within the company that were relied on by regulatory, quality

engineering, marketing, a whole host of issues. Every major issue in this case, it ended up on Charlotte Owens' desk. And Dr. Owens' testimony, she certainly can testify to her understanding of the processes and then focus her opinions down.

I was talking about design control before. Number one, her opinion is they did not come close to evaluating all of the potential risks and adverse events that could have resulted from the Prolift. Chapter and verse. And she has more than enough qualification to give those opinions, because Charlotte Owens was the one who signed off.

Number two, the clinical expert report, which we've been through in this trial now, she absolutely is qualified to talk about the inadequacy of that clinical expert report as an evaluation of the available clinical evidence at the time and whether or not that clinical evidence provides a favorable risk/benefit ratio such that the Prolift should have been cleared by Charlotte Owens of medical affairs to go to PRA and be marketed. Her opinions will be couched within her expertise and within her profession and her specialization.

When it comes to study design, nobody is going to argue with her qualifications. She started

the area in the NIH to fund NIH studies of urogynecologic surgery and disorders. She is more than qualified to comment on the clinical studies that were performed. If counsel wants to say it goes to the weight, because she hadn't personally done a study of the Prolift or of mesh, hey, have at it. I think it's going to be more than apparent to the jury that her expertise, which was brought to this and reading hundreds and hundreds of thousands of pages of internal documents, reading every single deposition in this case by every person involved, reading a pile of medical literature that is astounding, she has spent over 2,000 hours working on this case. That's more than 83 consecutive days. And they're going to put on experts who haven't looked at any of these materials.

So she has more than adequate basis and more than adequate -- and we're talking about now about her expertise, but any opinion -- and, again, medical affairs, clinical study and design, that is exactly what she is.

THE COURT: Well, it appears to me that you've addressed any concerns raised about her ability to testify about everything that happened within the company as far as their studies, whether they were adequate, inadequate. She's obviously a specialist in

designing studies and evaluating, and she has the educational background and the ability to do that. The fact that she herself has not designed a product, those all go to the weight of her testimony.

The only area that I'm concerned about is the regulatory and the 510(k) approval and -- because she really doesn't see --

MR. SLATER: I'll tell you what -- I'm sorry to interrupt, because I know time is valuable.

THE COURT: Let us know what we're going to do with that.

MR. SLATER: This is what she's going to say. She is not going to provide an opinion that they needed to get 510(k) clearance. Okay? That's Dr. Pence, who is going to testify next week.

But there's two areas that she is more than qualified and a few areas that relate to that.

Number one, the question of whether or not Gynemesh and the Prolift are essentially the same thing. She's certainly qualified to talk about the differences from a clinical standpoint in terms of the surgical procedures, in terms of how this would interact with the body, in terms of the -- now you're taking -- she can certainly differentiate them, not in a regulatory standpoint, but from a medical surgical

standpoint, what a surgeon would think when looking at these and say what's the same, what's different. And that's one thing.

THE COURT: She's someone who is an expert in surgical procedures, and I have no problem with her testifying to the difference in the surgeries between the two, whether she's performed them or not, and in the difference in the -- well, the difference in the procedures, the difference in the complications, the difference in the way they're performed, the differences in between the materials themselves, that she would be qualified to do.

When it gets into did this -- what is 510(k), how would -- do you intend to address the FDA with her?

MR. SLATER: The only way that I intend to address that question is this. She's aware of the regulatory status. It's a fact in the case. There's documents and there's testimony that establishes what happened at what time. I will ask her, does she have an opinion as to whether or not a reasonable urogynecologist, gynecologist or urologist, what they would have done if they knew the facts. Would it be significant to a surgeon to know that a product or a system, the Prolift, was or was not cleared if that was

necessary. I'm going to ask her to assume certain facts and say, assuming those facts, do you have an opinion as to whether a reasonable surgeon in this field would or would not use any medical device knowing that. And, in fact, she doesn't have to only rely on something in the abstract, she has the testimony of Dr. Benson, the implanting surgeon, who says I wouldn't have used it. She has the testimony of Vincent Lucente, their US investigator, their most important key opinion leader, says, I wouldn't have used it, I didn't know. David Robinson, their medical affairs director, who says, I would have had to take a close look at it, who while he was an investigator and then was using the product after launch, never knew it didn't have clearance.

So she has facts to rely on from multiple people who were employed by the company. Axel Arnaud parenthetically found out last year it wasn't cleared.

So she has the absolute ability to give that opinion of what a surgeon in this field would or would not have thought was significant in whether to do a surgical procedure. She has more than enough of a foundation for it. And she's not going to give an opinion as to whether or not 510(k) clearance was needed or not. Not her field, not going to ask the

question.

MS. JONES: That is absolutely irrelevant in this case. What's important in this case is what Dr. Benson testified to, period. And she -- what any reasonable surgeon other than Dr. Benson --

MR. SLATER: Then I ask for a directed verdict on failure to warn and deceit right now. I'd like a directed verdict. If counsel says the only thing that matters is what Dr. Benson said, his trial testimony is locked in stone now, he said he wouldn't have used it. Therefore, I ask for a directed verdict.

MS. JONES: That is -- Your Honor, his testimony will come in at the appropriate time in the appropriate manner when Your Honor rules.

Now, the --

THE COURT: Well, the argument as to whether it was, quote, experimental to a degree or whether it was in fact simply an extension of a prior procedure that had been done, I think first -- I think that clearly falls within her expertise as a surgeon who's performed numerous different types of surgery and who specialized in the type of repairs that we're talking about, so I'm going to allow her to do that.

As to whether what a reasonable surgeon would do if advised, I think that is part of it and is

appropriate. Obviously, the jury is going to give great weight, I'm sure, to what Dr. Benson said, but in evaluating the credibility of Dr. Benson and evaluating the statements that were made by him, I think that part of her expertise goes to what surgeons would have understood, would not have understood, what they would have wanted to know, why they would have wanted to know it. She's coming at it from the point of view of a surgeon. I'm going to allow her to give that testimony.

All right. We'll proceed. And if there's any objections to any particular questions, you can make them, obviously. And the objection to her speaking about the regulatory process is -- I'm sustaining that objection as far as the process itself, as far as what the process is, what the 510(k) requires, what -- whether they did or did not comply. Counsel's indicated she's not going to be asked about that, and so the regulatory process, I think, which she has limited qualification in, I grant that motion.

The motion as to the design of the product itself and whether a surgeon would have been able to work with it and how it would affect, I'm going to allow. All right.

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